

## ULTRASONIC IMAGING DEVICE, SYSTEM AND METHOD OF USE

This application claims priority under 35 U.S.C. §119(e) from United States provisional patent application serial number 60/442,034, filed on January 23, 2003, which is incorporated herein by reference, in its entirety.

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### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

The present invention relates to apparatus used for ultrasonic imaging. More particularly, it relates to apparatus for simultaneous imaging in both longitudinal and transverse views. More specifically, it relates to apparatus for imaging for purposes of medical diagnosis and treatment, especially for diagnosis and treatment of organs such as the prostate.

#### 2. Prior Art

15 There are various situations in which it is necessary to do ultrasonic imaging to assist in medical diagnosis and treatment. For example, prostate cancer is one of the most common cancers found in men. Treatment options include "watchful waiting", hormonal therapy, brachytherapy, or surgery. Three types of surgery are used. The classical "open" procedure, radical prostetectomy, and the newly developed laproscopic and cryosurgery procedures. All procedures have risks. Both the open procedures and the laproscopic procedures have significant risks of causing impotence and incontinence. With both brachytherapy, and cryosurgery the prostate is

left in vivo, and therefore the risk of complications is much lower, and the recovery time is quicker.

5 In brachytherapy, trains of seeds are implanted in rows in the prostate. Cryosurgery is done in a similar fashion, except that cooling needles are inserted in eight to twelve locations in the prostate. Cold gases are circulated through the needles, and the prostate is monitored by ultrasound imaging for the formation of ice  
10 balls, which indicates proper operation of the device. Both of these procedures may be preformed under local anesthetic.

As illustrated in Fig. 1, ultrasound guidance is used in  
15 order to properly locate the needle holding the seeds for brachytherapy or the needles for cryosurgery. In Fig. 1, those skilled in the art will recognize the following bladder B, prostate P, urethra U, rectum R, perianal wall Pe, operator 10, ultrasonic probe 12, needle grid block  
20 14, needle 16, needle core 18, and seeds 20.

As illustrated in Fig. 2, in the prior art, the typical bi-plane ultrasonic probe 22 used has a linear transducer array 24 to image the sagittal or longitudinal view, and a  
25 micro-convex curved array 26 for the transverse view. The linear array is usually 50 mm long, and is not long enough to visualize the entire prostate in many patients.

As illustrated in Fig. 3, the micro-convex array 26 is at  
30 the end of the probe, and its imaging plane 28 does not intersect the linear array's imaging plane 30. This causes the operator to have to constantly move the probe

to different positions along the rectum during the procedure. This is time consuming, and more importantly, causes the prostate to move, leading to more uncertainty as to where the seeds are being placed.

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#### SUMMARY OF THE INVENTION

It is an object of the invention to provide an ultrasonic probe that allows the entire prostate to be visualized at once.

10 It is a further object of the invention to provide an ultrasonic probe that may be used to place the transverse scan in the middle of the prostate, thus eliminating the need to change the longitudinal position of the transducer along the rectum, and requiring rotation,  
15 which does not move the prostate significantly.

It is yet another object of the invention to allow for more accurate and quicker needle placement for brachytherapy and cryosurgery when using a standard brachytherapy and cryosurgery apparatus.

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It is still another object of the invention to provide an ultrasonic probe that allows for the entire prostate to be imaged simultaneously in both longitudinal and transverse views.

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These objects and others are achieved in accordance with the invention by providing a bi-plane transducer where three independent arrays are mounted. There are two curved arrays typically subtending 30 degrees of arc of

typically 60 mm radius mounted longitudinally on the housing, with a micro-convex array of typically 10 mm radius mounted transversely between the two larger curved arrays.

5 The ultrasound system used with this ultrasonic probe can be used scan all three arrays sequentially. The two convex arrays are used to create one continuous image of the longitudinal plane. The micro-convex transducer images the transverse plane. Both images can be  
10 displayed simultaneously on the system monitor. At least one high voltage multiplexer integrated circuit may be built into the handle to switch the system electronics between the three different arrays of the probe. At least one additional multiplexer may be used to switch  
15 between the above mentioned probe and another probe.

The present invention is also directed to the combination of the new ultrasonic probe described herein, and an electronics package or module to which the probe is connected. As is known in the art, such package or  
20 module serves to excite and control the transducer arrays of the ultrasonic probe, process signals representative of ultrasonic reflections received by the transducer arrays from structures within a subject or patient, form images in accordance with the processed signals, and  
25 display the images for viewing by appropriate personnel.

The invention is also directed to a method of using an ultrasonic probe, and in particular, the ultrasonic probe in accordance with the invention, and the associated electronics package or module (in combination, the

ultrasonic system) to image two intersecting planes within the subject or patient. Preferably, an entire organ (such as the prostate) is viewed, without having to reposition the probe (along the length of the rectum, in the case of the prostate).

Thus, the invention is directed to an ultrasonic probe comprising an elongate structure having a longitudinal axis; a first array of ultrasonic transducer elements extending along an outer surface of the elongate structure in a direction generally parallel to the longitudinal axis; a second array of ultrasonic transducer elements extending along the outer surface of the elongate structure in a direction generally parallel to the longitudinal axis; and a third array of ultrasonic transducer elements extending about the elongate structure in a direction so that it images a plane perpendicular to that imaged by at least one of the first array and the second array, the third array being disposed in a space between the first array and the second array.

The first array, the second array and the third array are preferable outwardly convex. The third array preferably has a radius of curvature smaller than that of the first array and the second array. The first array and the second array may be configured so that beams formed by the first array and the second array subtend substantially thirty degrees of arc. The third array may be configured so that a beam formed by the third array subtends substantially one hundred eighty degrees of arc.

The probe may further comprise a multiplexer for multiplexing connections to each of the first array, the second array and the third array. The multiplexer may be disposed within the elongate structure.

- 5 The first array and the second array are preferably aligned so as to image a portion of a substantially continuous plan perpendicular to the plane imaged by the third array.

10 The invention is also directed to the above described probe in combination with a second probe, the second probe being capable of positioning so as to imaging in a plane perpendicular to a plan imaged by the first array and a plane imaged by the second array.

15 The invention is also directed to one or both of the above described probes in combination with an electronics module, comprising excitation circuitry for providing excitation energy to the probe; receiving circuitry for processing signals received by the probe; signal processing circuitry for processing signals from the receiving circuitry to produced processed image signals; and a display for displaying the processed image signals. The combination may further comprise at least one of: frequency setting circuitry for setting a frequency of the excitation energy; depth control circuitry for controlling the depth of images produced on the display; gain control circuitry for controlling gain of the receiving circuitry; and steering and focus control circuitry as a component of the signal processing circuitry for controlling the manner of operation of the signal processing circuitry. The excitation circuitry

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may comprise a table memory for providing values of waveforms used to excite transducer elements of the probe. The combination may further comprising analog to digital converters as components of the signal processing circuitry for converting analog signals from the receiving circuitry into digital signals.

The invention is also directed to an ultrasonic imaging system comprising: a first probe having an elongate structure having a longitudinal axis; at least a first array of ultrasonic transducer elements extending along an outer surface of the elongate structure in a direction generally parallel to the longitudinal axis; an additional array of ultrasonic transducer elements extending about the elongate structure in a direction so that it images a plane perpendicular to that imaged by the at least one first array; a second probe having a further transducer array, the second probe capable of being positioned so as to imaging in a plane perpendicular to a plan imaged by the first array and the plane imaged by the additional array; and an electronics module, the module having the components mentioned above, including the excitation circuitry, receiving circuitry, signal processing circuitry; and a display for displaying processed image signals.

The first probe may further comprise a second array of ultrasonic transducer elements extending along the outer surface of the elongate structure in a direction generally parallel to the longitudinal axis, the second array also being excited by the excitation circuitry.

The additional array is preferably disposed between the first array and the second array.

5 The system may further comprise at least one multiplexer for connecting each of the first array, the additional array and the further array to the electronics module for display of images.

10 The at least one multiplexer may comprise a first multiplexer for switching the electronics module between the first probe and the second probe; and a second multiplexer for switching between transducer arrays of the first probe.

15 The first multiplexer may be a four to one multiplexer, which switches to a first half of transducer element of the further array, a second half of transducer elements of the further array, a first half of transducer element of a selected one of the arrays in the first probe, and a second half of transducer elements of the selected array in the first probe. The second multiplexer may switch the selected array to be one of the first array and the additional array. When the probe comprises a second array extending along the outer surface of the elongate structure, the second array may also be excited by the excitation circuitry, and the second array may be one of the selected arrays.

25 The invention is also directed to a method for medical ultrasonic imaging comprising placing a first probe having transducer arrays which image in two mutually perpendicular directions in a body cavity of a patient; placing a second probe on an exterior surface of the patient so that a transducer array of the second probe

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produces an image in a plane perpendicular to each of the two mutually perpendicular planes; exciting the probes; and forming images using signals from the probe to visualize structures within the patient. The first probe  
5 may have the structure described above.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing aspects and other features of the present invention are explained in the following description, taken in connection with the accompanying drawings,  
10 wherein:

Fig. 1 is a cross-sectional view of a patient with an ultrasonic probe in the rectum held in a brachytherapy device, and with an additional imaging probe.

Fig. 2 is a perspective view of a prior art ultrasonic probe with a prior art transducer assembly.  
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Fig. 3 illustrates the scan planes of the prior art device of Fig. 1.

Fig. 4 is a perspective view of the operative end of an ultrasonic probe in accordance with the invention.

Fig. 5 is a cross sectional view of the embodiment of the invention illustrated in Fig. 4.  
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Fig. 6 illustrates the scan planes of the ultrasonic probe in accordance with the invention.

Fig. 7 is block diagram of a system using the ultrasonic probes, in accordance with the invention.  
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## DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring again briefly to Fig. 1, in accordance with the invention, an additional ultrasonic imaging probe 19 may be placed on the abdominal wall of the patient 21 to  
5 image the prostate P from above. Probe 19 may have an array of, for example 128 transducers, in a flat or slightly concave configuration, and thus may be suited to image structures through the abdominal wall of the patient. The coordination of images produced by  
10 ultrasonic probe 42 and probe 19 is explained below with respect to Fig. 7. Due to the location of probe 19, with the consequent need for the ultrasound produced and received by probe 19 to traverse a larger distance to and from the prostate than the ultrasound from probe 42,  
15 probe 19 may operate at a frequency lower than that used to excite the elements of the transducers of probe 42, or, in some applications, at the same frequency.

Referring to Fig. 4, there is shown a perspective view of  
20 the operative or distal end portion 40 of an ultrasonic probe 42 incorporating features of the present invention. Although the present invention will be described with reference to the single embodiment shown in the drawings, it should be understood that the present invention can be  
25 embodied in many alternate forms of embodiments. In addition, any suitable size, shape or type of elements or materials could be used.

Referring also to Fig. 5, ultrasonic probe 42 includes a substantially hollow probe housing 44 having a handle 46,  
30 a flexible cable guide 47 for a multi-wire cable (not shown in Fig. 5) a connecting tube 48, and end portion

40. These components (except for cable guide 47) may be constructed of a high strength engineering plastic, which retains its properties after multiple exposures to the heat required for cleaning and sterilization. End  
5 portion 40 has a solid insert 49, formed of an insulating material, and designed to support appropriate connecting wires (not shown) and three transducer arrays, as described below.

10 The three transducer arrays of end portion 40 are for emitting and receiving ultrasound for the purpose of imaging the organs of a patient, and in particular, the prostate of a patient. These transducer arrays include a first convex array 50, a second convex array 52, and a micro-convex array 54.

15 Transducer arrays 50 and 52 may each comprise 96 piezoelectric elements, having a pitch of 0.327 mm, an elevation of 5 mm, and a focal distance of 30 mm. Each array may subtend 30 degrees of arc, of a 60 mm radius of curvature. The frequency of resonance of the  
20 piezoelectric elements may be 6.5 MHz.

Micro-convex transducer array 54 may include 128 elements. Alternatively, it may include 96 elements on a pitch of 0.215 mm, having an elevation of 5 mm and a focal distance of 30 mm, with the beam formed subtending  
25 an angle of 180 degrees. The frequency of resonance of the piezoelectric elements may be 6.5 MHz.

As noted above, multiplexing electronics may be located in handle 46 of housing 44. A cable (not shown in Fig. 5) having a 156 pin connector, such as a Cannon ZIF  
30 connector, may be used to connect the electronics to an

electronics module (Fig. 7) so that images may be generated and viewed.

Fig. 6 illustrates the relationship between the sagittal or longitudinal scan planes 60 and 62 generated by arrays 50 and 52 respectively, and the transverse scan 64 generated by micro-convex curved array 54. It is noted that scan planes 60 and 62 are co-planar and partially overlap, thus permitting the entire prostate to be imaged along a single longitudinal plane without moving probe 42 in the rectum of the patient. Micro-convex transducer array 54 provides an image in a transverse scan plane 64 that is perpendicular to scan planes 60 and 62. The location of transducer array 54 between transducer arrays 50 and 52 means that the center of the prostate may be imaged in the transverse plane at the same time as the entire prostate is imaged in the longitudinal plane. In other words, the transducer arrays are aligned, or positioned with respect to one another, so that the transverse imaging array produces an image at (or in the general case, near) the center of the longitudinal image.

Referring to Fig. 7, ultrasonic transducer 19 and ultrasonic probe 42 are connected to an electronics module 100, which contains the circuitry necessary to excite the ultrasonic transducer 19 and ultrasonic probe 42 so as to send pulses of ultrasound into the patient, receive ultrasound reflected from internal structures and organs, and convert the signals, in a desired fashion to an image or images which may be interpreted in a medically significant fashion. In general, such modules are well known in the art. However, the use of

ultrasonic transducer 19 and ultrasonic probe 42 gives rise to a unique arrangement of components.

In general, module 100 may be controlled by a microprocessor 102 connected by suitable lines 103 to a control input 104. Microprocessor 102 and control input 104 may be dedicated, hardwired components (such as a control panel with appropriate switches and knobs for control input 104) within module 100, or may represent, for example a personal computer and a keyboard, respectively, interfaced in a manner well know in the art to the remainder of module 100. If this is the case, suitable software may be provided to allow the keyboard to provide the control inputs typically provide in a module 100, such as brightness, contrast, color control, and control over parameter such as frequency of operation, focus, beam steering, system gain, and other necessary parameters, as more fully described below. In a like manner, a video processor 106 and a display 108 may also be dedicated components of the module 100 or the video driver card and monitor of the personal computer.

Frequency control inputs provided by control input 104 are processed by microprocessor 102 and provided in suitable form to a frequency control 110. An output of frequency control 110 determines the rate at which entries in a table memory 112 are read out to each of sixty-four different transmitter channels represented as 114. Table memory 112 includes a multidimensional array of waveform values. The values that are read out for one of the dimensions is determined by a depth control 116, in response to inputs from microprocessor 102, as

determined by input from control input 104. Thus the depth of display desired may be adjusted.

5 The outputs of the transmitter channels are supplied to a transmit/receive switch 118, which is in turn connected to a 4:1 multiplexer or MUX 120 and sixty-four receiver channels, as represented by 122. The transmit/receive switch 118 serves to switch the sixty-four inputs of 4:1 MUX 120 between transmitter channels 114 and receiver channels 122 in a manner well known in the art.

10 The 4:1 MUX 120 serves to switch the 64 transmitter and receiver channels between 128 elements of transducer 19 (sixty four elements at a time) and the 96 elements of one of the transducer arrays of ultrasonic probe 42. In other words, there are 256 outputs on one side of MUX 120  
15 (the side connected to the cables to transducer 19 and probe 42) and 64 on the other side connected to transmit/receive switch 118. However, in the case of probe 42, some of the outputs are not used. MUX 120 may be a high voltage, low impedance switching multiplexer,  
20 such as that manufactured by Supertex, Inc., located in Sunnyvale, CA, USA.

A second multiplexer or MUX 124 (in this case a 3:1 multiplexer located in the handle of probe 42) having 128 ports on each side, is used to successively connect 96  
25 outputs of MUX 120 to the respective element of the three transducer element arrays of probe 42 described above. MUX 124 may be of the same general type as MUX 120.

Receiver channels 122 provide suitable amplification and conditioning of analog signals returned by transducer  
30 elements of transducer 19 and probe 42 in response to

reflections of ultrasound by structures within the patient. Gain control signals are provided to receiver channels 122 by a bus 125. The analog signals are converted to digital form by a series of sixty-four  
5 analog-to-digital converters or A/D's 126. As is well known in the art, the number of A/D output signals used to form an image is a function of depth of the image, generally with more channels being used for imaging at greater depth. A beam steering and focusing circuit 128  
10 process the digital signals from the A/D's 126. The outputs of beam steering and focusing circuit 128 are provided to video processor 106 to provide a suitable representation of the patient on display 108.

Microprocessor 102 has appropriate outputs 130 and 132  
15 for controlling MUX 120 and MUX 124, as required to perform the sequence of switching described herein.

The images provided on display 108 advantageously include those provided by the three transducer arrays of probe 42, as discussed above. In addition, an image generated  
20 by signals from probe 19 may also be displayed, preferably above the image resulting from the signals from probe 42. Thus, in addition to imaging the transverse plane and the entire longitudinal plane of an organ, such as the prostate, or a defined region, a top  
25 view may be displayed as well. The various images, when taken together, provide an excellent, very precise view of the organ or image in three dimensions, allowing the precise location of structures and therefore the accurate placement of, for example, seeds or needles, for  
30 brachytherapy or cryosurgery, as described above.

It should be understood that the foregoing description is only illustrative of the invention. Various alternatives and modifications can be devised by those skilled in the art without departing from the invention. Accordingly,  
5 the present invention is intended to embrace all such alternatives, modifications and variances which fall within the scope of the appended claims.